

Remarks

Claims 34-38 and 40-41 are pending.

Claim 34 has been amended to include an "epicardial" near surface and an "endocardial" far surface. Dependent claim 35 has also been amended to include an "epicardial" near surface and to remove the "positioning step" element which is redundant with the same element in claim 34. Support for these amendments can be found in the specification as a whole and, for example, at pages 34-35 and Figure 53.

No new matter is added by these amendments.

Rejections under 35 U.S.C. § 102(e)

Claims 34-36 and 38 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Rittman.

Claims 34-36 and 38 have been rejected by the Examiner as allegedly being anticipated by Rittman, III, et. al. The Examiner notes that in Rittman the treatment is ablation and the temperature or flow of blood is used as one of the controlling parameters of the energy application.

Applicants respectfully submit that the Examiner has not made out a *prima facie* case for anticipation.

Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. In re Dillon, 919 F.2d 688, 16 USPQ2d 1897. 1908 (Fed. Cir. 1990) (en banc). The identical invention must be shown in as complete detail as is contained in the claim. Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236; 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). See also MPEP 2131.

Applicants' claim 34 (prior to the amendment here) recites "positioning the [ablating] device at a tissue site, the tissue site having a near surface and a far surface; measuring a temperature change at the tissue site over a period of time; analyzing the temperature change to provide a tissue characterization; and ablating the tissue in response to the tissue characterization"

Applicants can not find any reference in Rittman to the element of "positioning" the ablating device at a "tissue site having a near surface and a far surface." This omission is not surprising when one examines the actual contents of the Rittman document. Rittman discusses a "Cool-Tip Radiofrequency Thermosurgery Electrode System for **Tumor Ablation**" (emphasis added). Although the treatment in Rittman is ablation, the nature of the tissue being ablated - a tumor - is very different and therefore calls for entirely different methods of ablation, as one of ordinary skill in the art recognizes.

Applicants' specification, drawings and claims are, in one embodiment, directed to an ablation catheter which rests on a tissue site having two specific kinds of tissue *surfaces*, in this case an epicardial surface and an endocardial surface. The ablating device is placed on a near surface and energized in a manner that ablates the tissue from a that near surface through to a far surface. One objective is to create **elongated** transmural lesions surrounding the pulmonary veins. (See Specification at Page 1, Lines 33-35 and Figure 11).

In contrast, Rittman specifically discusses ablating a **volume** of tumor tissue. Figures 8 and 9 of Rittman, cited by the Examiner, clearly illustrate the contrast. In Rittman, the catheter "has a closed, pointed tip . . . which aids in **penetration**" of the tumor surface to a predetermined position **within the tissue**. The ablation then proceeds outward in a three-dimensional, **volumetric** manner. (Rittman at col. 4, lines 18-20, emphasis added). The Examiner fails to identify any part of the tumor tissue that could form a near surface and a far surface, as recited in the claims. Rittman makes

clear that the ablating point probe actually **penetrates** the surface. For this reason alone, Rittman does not recite each element of Applicants' claim and is not the identical invention.

Without waiving any argument that the rejection over Rittman is improper, Applicants have amended claims 34 and 35 to recite an "epicardial tissue site," "epicardial near surface" and an "endocardial far surface."

In addition to the positioning step, the rejection based on Rittman overlooks another distinctive feature of Applicants' claims. The Examiner cites to Rittman "wherein the treatment is ablation, and the temperature or flow of blood is used as one of the **controlling parameters of the energy application.**" (Office action at page 2). Applicants' independent claim 34 is directed to "measuring a temperature change at the tissue site over a period of time; analyzing the temperature change to provide a tissue characterization; and ablating the tissue **in response to** the tissue characterization."

Applicants' specification, in one embodiment, clearly describes the measuring of the temperature change which provides the tissue characterization. (Applicants' specification at p. 34, line 25 to p. 35, line 30). It comprises a slow, non-ablating heating (or cooling) step which is monitored over time in order to determine the thermal response of the cardiac tissue (its tissue characterization). The proper ablating temperature and time course is then calculated from the measured tissue characterization and related to a list of other "variables consisting of presence of fat, amount of fat, flow rate of blood, tissue thickness and temperature of blood." (Applicants' claim 34). Look-up tables or calculations are employed to determine the proper ablation procedure. Applicants' claim 36 also illustrates that the tissue characterization step is distinct from the ablation step: ". . . the method also including *the step of changing the temperature of the tissue* with the ablating element; and *the ablating step* is carried out with the ablating element."

In contrast, a closer reading of Rittman shows that the monitoring of temperature and blood flow occurs during the ablation step itself. In Rittman, this monitoring is meant to provide the physician with a safety control rather than helping to plan the type of ablation that will be performed in a later step. In the passages cited by the Examiner, Rittman discusses using the temperature monitoring “to visualize the time rate of change or temporal derivatives as *the procedure* goes forward in time, giving the surgeon an *instantaneous sense* of the correctness or possible problem with the heating such as *transient boiling or runaway to higher temperatures.*” Rittman at col. 19, lines 20-24. Similarly, Rittman uses impedance monitoring as a “measure of the uniformity of heating, the change of the tissue characteristic *in the ablation process*, the onset of boiling, incipient or local boiling, gas formation, charring, etc.” (Id. at col. 19, lines 43-45). Finally, Rittman discusses using MRI imaging to observe blood flow but also makes clear that it is doing so to monitor “the shutting off of blood perfusion *during the thermal ablation process.*” (Id. at col. 27, lines 21-25).

Although the Examiner alleges that Rittman may use “temperature or flow of blood as one of the controlling parameters of the energy application,” Applicants’ claims make clear that measuring and analyzing the temperature change at the tissue site is a step that is distinct from the ablation energy application. Applicants’ invention provides a tissue characterization from measured data of the patient’s own heart before the ablation begins and then analyzes the data to set the parameters of the ablation step that will follow. Therefore, once again, Rittman does not contain all of the limitations found in Applicants’ claims as required to sustain a rejection based on anticipation.

Applicants respectfully request withdrawal of this rejection.

Rejections under 35 U.S.C. § 103(a)

Claims 34, 37 and 40 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rittman in view of Swanson.

The Examiner has rejected claims 34, 37 and 40 as being obvious over the combination of Rittman in view of Swanson. The Examiner alleges that Rittman “teaches a method such as claimed except epicardial placement and activation of no more than half the ablating elements. Swanson . . . teaches the desirability of ablating on the epicardium and that less than half the total number of electrodes can be used.”

Applicants have argued above that Rittman does not contain the “tissue characterization” step as required by the claims. Swanson also does not contain or suggest a “tissue characterization” step. Therefore Applicants assert that the combination of Swanson and Rittman fail to teach or suggest Applicants’ invention.

In order to make out a *prima facie* case of obviousness, “the Examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.” In re Rouffet, 149 F.3d 1350 (Fed. Cir. 1998). Additionally, “[t]he initial burden is on the Examiner to provide some suggestion of the desirability of doing what the inventor has done.” In re San Su Lee, 277 F.3d 1338 (Fed. Cir. 2002). The evidence of record must identify an objective source for the motivation to combine Rittman with Swanson in the manner proposed.

The Examiner has specifically alleged that the skilled artisan would “employ the method of Rittman . . . in the method of Swanson, since this would enable the determination of the state of inflammation and thus the need for treatment of fatty deposits which exist on the epicardium, as taught by Swanson . . . or to include the method of Swanson . . . in the method of Rittman . . . since the method of Swanson . . . is applicable to both intravascular and extravascular treatments, thus producing the method such as claimed.” (Office action at page 3).

Respectfully, Applicants can find no reference in either Rittman or Swanson to a “determination of the state of inflammation” and respectfully request clarification of this

rejection. The language used in the rejection is identical to the language used in previous Office actions which combined Swanson with Brown in different obviousness rejections (Office action of October 14, 2003 at pg. 3; Office action of July 28, 2004 at pg. 2). Brown is directed to a "Device and Method for Locating Inflamed Plaque in an Artery". Since Brown is the only reference that determines a "state of inflammation," Applicants' respectfully assert that a *prima facie* case has not been made for the combination of Rittman with Swanson.

Without waiving future arguments regarding alleged motivations for combining these references, Applicants assert that there would be no motivation for a skilled artisan to combine Rittman with Swanson when faced with the problem that the present invention addresses – how to plan the ablation of cardiac tissue.

Applicants' invention, in at least one embodiment, is directed to a method of delivering energy for a cardiac surface ablation. As noted above, nowhere does Rittman teach or suggest a method to produce a surface ablation. Swanson recites a method for performing a surface ablation on the heart in order to treat atrial fibrillation. In particular, long, thin lesions of different lengths and curvilinear shapes in heart tissue are discussed (See Swanson col. 3, lines 33-40). A person of ordinary skill in the art would have no motivation to consider methods for performing a volume ablation on a tumor when considering precise surface ablations to treat atrial fibrillation. In fact, Swanson specifically addresses this issue.

Swanson discusses the problems associated with using conventional ablation catheters for ablating cardiac tissue. Chief among these problems is over-heating the tissue which can cause coagulum and charring.

One proposed method of solving the over-heating problem associated with conventional ablation catheters is the so-called "cooled tip" approach. Here, the tissue surface is cooled with a saline solution. Although the saline is somewhat useful in keeping the surface temperature below the over-heating temperature, the

sub-surface temperature can still rise well above 100° C. Such temperature will cause gas within the sub-surface tissue to expand. Ultimately, the tissue will tear or pop, which will result in perforations of the epicardial surface and/or the dislodging of chunks of tissue that can cause strokes. (Swanson at col. 4, lines 21-31).

As its title and specification indicate, Rittman is an example of the "cooled tip" approach which Swanson specifically says has dangerous implications for ablating a cardiac surface. Indeed, a look back at Rittman after reading Swanson would show that Rittman has no discussion of ablating cardiac surfaces at all.

Swanson further states that "it is believed the treatment of atrial fibrillation and flutter requires the formation of *long, thick lesions of different lengths and curvilinear shapes* in the heart. Such *long curvilinear lesion patterns* require the deployment within the heart of *flexible ablating elements* having *multiple ablating regions*." (Swanson at col. 3, lines 32-37). The skilled artisan looking back at Rittman at this point would again see Rittman's single point probe stuck through the surface of a tumor and ablating outward in all directions.

The Examiner also alleges that Swanson "teaches the desirability of ablating on the epicardium." Once again, a closer reading of Swanson shows that although it may be desirable to ablate on the epicardium, "[i]t is, however, very difficult to achieve suitable contact between the tissue and the electrodes. Thus, it is preferable to perform endocardial ablation around or between the pulmonary veins in the manner described below." (Swanson at col. 43, line 64-67). The plain words of Swanson would discourage one of ordinary skill from pursuing Swanson as a device suitable for epicardial ablation. A prior art reference may be considered to teach away when "a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." In re Gurley, 27 F.3d 551, 553 (Fed. Cir. 1994).

"Recognition of the problem of treating complex heart arrhythmias does not render obvious the eventual solution. Recognition of a need does not render obvious the achievement that meets that need. There is an important distinction between the general motivation to cure an uncured disease (for example, the disease of multiple forms of heart irregularity) and the motivation to create a particular cure." Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., 381 F.3d 1371 (Fed. Cir. 2004).

Swanson specifically states that the cooled-tipped approach found in Rittman's tumor ablating device is inappropriate for ablations of cardiac tissue. "When prior art references require selective combination . . . to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself." (emphasis added) Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143 (Fed. Cir. 1985).

Applicants respectfully reassert that the combination of Rittman and Swanson do not teach or suggest Applicants' invention. Respectfully, the Examiner has not made out a *prima facie* case for obviousness because no motivation has been presented for the selective combination of elements from Rittman and Swanson, which the skilled artisan would recognize as presenting elements that are diverging from each other and from Applicants' claimed invention.

Applicants respectfully request withdrawal of this rejection.

Claim 41 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rittman in view of Ben Haim.

Claim 41 has been rejected as being obvious over Rittman and Swanson and further in view of Ben Haim. The Examiner alleges that Ben Haim "teaches drawing tissue into a suction well prior to ablation. It would have been obvious to employ the step of drawing the tissue desired into suction surrounding the ablating elements since

this allows the catheter to remain stable while the tissue is ablated, thus producing a method such as claimed. " (Office action at page 3).

As noted above, Applicants have argued that neither Rittman nor Swanson contain or suggest the element of a "tissue characterization" step and therefore their combination does not teach or suggest Applicants' invention. Applicants further assert that Ben Haim also does not contain or suggest a "tissue characterization" step as required to sustain the rejection.

Also, as argued above, Rittman does not teach or suggest any type of surface ablation. The nature of the ablating element in Rittman – a point probe which actually penetrates the surface of the tumor and is surrounded on all sides by target tissue – means that it does not present the same problem which Ben Haim is intended to solve. Once again, the skilled artisan looking to improve electrode contact during a surface ablation would have absolutely no motivation to look to a non-surface ablation method like Ritmann. The point probe of Rittman is already stabilized on all sides by the tissue that it has penetrated and would have no use for a suction well. Ben Haim also does not remedy any of the deficiencies in Ritmann such as formation of coagulum or charring. Thus, as above, the Examiner has presented no motivation for the skilled artisan to combine these two widely diverging methods of ablation and therefore a § 103 rejection is improper. Applicant respectfully requests withdrawal of this rejection.

Claims 34-38, 40, and 41 stand rejected under the doctrine of obviousness-type double patenting over claims 7 and 8 of US patent 6,971,394.

The Examiner has asserted that Applicants' claims are obvious variations of specific claims in US patents 6,971,394, but has not offered any detail as to why a person of ordinary skill in the art would come to that conclusion. Applicants respectfully note that independent claim 34 of the application includes measuring and analyzing temperature changes of the tissue over time to provide a tissue characterization while

the cited claims of US 6,971,394 are directed to a step method of ablating cardiac tissue including a guide member and an ablating member with a focus.

Claims 34-38, 40, and 41 stand rejected under the doctrine of obviousness-type double patenting over claims 9 and 10 of US patent 6,805,129.

The Examiner has asserted that Applicants' claims are obvious variations of specific claims in US patents 6,805,129 but has not offered any detail as to why a person of ordinary skill in the art would come to that conclusion. Applicants respectfully note that independent claim 34 of the application includes measuring and analyzing temperature changes of the tissue over time to provide a tissue characterization while the cited claims of US 6,805,129 are directed to a method of ablating cardiac tissue with focused ultrasound at two different frequencies.

Claims 34-38, 40, and 41 stand rejected under the doctrine of obviousness-type double patenting over claims 19, 20, 24, 25, 34, 35, 39, 40, 50 and 51 of US patent 6,645,202.

The Examiner has asserted that Applicants' claims are obvious variations of specific claims in US patents 6,645,202 but has not offered any detail as to why a person of ordinary skill in the art would come to that conclusion. Applicants respectfully note that independent claim 34 of the application includes measuring and analyzing temperature changes of the tissue over time to provide a tissue characterization while the cited claims of US 6,645,202 are directed to a method of ablating cardiac tissue with focused ultrasound at two different frequencies.

Applicants request withdrawal of the Examiner's rejections and submit that the application is in condition for allowance. Timely notification of allowability is requested.

Application No: 09/507,336
Attorney Docket No. 82410.0027/0E-040013US
Response to Office action dated January 12, 2006
Reply and Amendment of July 12, 2006

Applicants have included a three month extension of time request and the appropriate fee with this response. No additional fees, requests for extension of time, other petitions, additional claim fees, or any other fees are believed to be necessary to enter and consider this paper. If, however, any extensions of time are required or any fees are due in order to enter or consider this paper or enter or consider any paper accompanying this paper, including fees for net addition of claims, Applicants hereby request any extensions or petitions necessary and the Commissioner is hereby authorized to charge our Deposit Account No. 50-1129 for any fees. If there is any variance between the fee submitted and any fee required, or if the payment or fee payment information has been misplaced or is somehow insufficient to provide payment, the Commissioner is hereby authorized to charge or credit Deposit Account No. 50-1129.

Respectfully submitted,

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Date: July 12, 2006

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